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KRIEG DEVault LLP ONE INDIANA SQUARE SUITE 2800 INDIANAPOLIS, IN 46204-2079			EXAMINER	
			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,897	Applicant(s) STRASSLER ET AL.
	Examiner KAREN E. TOTH	Art Unit 3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24-46 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 24-26 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/27/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26, 28, 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the magnet" in line 3. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, the claim will be treated as though reading "a magnet".

Claim 28 recites the limitation "the magnet" in line 2. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, the claim will be treated as though reading "a magnet".

Claim 32 recites the limitation "the magnet" in line 4. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, the claim will be treated as though reading "a magnet".

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 24-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Line 6 of claim 24 includes the limitation "worn externally on the skin". The human body may not be claimed. For the purposes of examination the claim will be treated as though reading "configured to be worn externally on the skin".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 24, 25, 27, 31, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Ballerstadt (US 7226414).

Regarding claims 24 and 31, Ballerstadt discloses a blood glucose concentration sensor system comprising an implantable sensor (element 12) and a user device (elements 24), where the sensor is a glucose-permeable ampoule containing a glucose-sensitive liquid and the viscosity of the combination of diffused glucose and the glucose-sensitive liquid is measured (column 3, lines 6-11; column 4, lines 51-66; column 5, lines 4-13), and where the user device is portable, is used to control the measurement

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and evaluation of the measurement, and is worn externally on the skin (figure 5; column 2, lines 27-36).

Regarding claim 25, Ballerstadt further discloses measuring the viscosity by monitoring oscillatory behavior of an oscillating element disposed in the sensor that is excited into oscillations by an oscillating magnetic field (column 6, lines 10-26; the movement between positions may be considered slow oscillations).

Regarding claim 27, movement of the oscillating element through the glucose and sensitive liquid would inherently cause mixing of the components – that is, homogenization.

Regarding claim 35, Ballerstadt further discloses using a magnet in the sensor to cause a measuring element to rotate (column 10, lines 15-25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 26, 28-30, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt in view of Wright (US 2003/0230136).

Regarding claim 26, Ballerstadt discloses all the elements of the claimed invention, as described above, except for the oscillatory behavior of the oscillating element being analyzed on its decay behavior after a magnet is turned off, where the

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oscillating element itself generates a measurable magnetic field. Wright teaches a system for measuring viscosity of a liquid using an oscillatory element excited by a magnet to create a magnetic field, where the decay behavior of the element is used to determine the solution's viscosity (abstract; paragraph [0009]), in order to generate an accurate measurement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Ballerstadt to measure the decay behavior of the oscillatory element to determine the solution's viscosity, as taught by Wright, in order to obtain an accurate measurement.

Regarding claim 28-30, Ballerstadt discloses all the elements of the claimed invention, as described above, except for the oscillating element being joined to a magnet and consisting of a bending bar, where the magnet is joined to an end of the bending bar and generates a magnetic field. The Examiner notes that "bending bar" is being used throughout the application but has not been defined; since the term is not one commonly used in the art, it will be given its broadest reasonable interpretation - that being a structure that can undergo flexion. Wright teaches a system for determining the viscosity of a solution comprising a bending bar (element 2) that is joined at one end to a magnet (element 36; figure 3) which oscillates (paragraph [0018]) in response to a electromagnetic field (paragraph [0024]-[0025]; abstract) in order to determine the viscosity of a solution surrounding the components. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Ballerstadt with the oscillating element comprising a bending bar and magnet, as

taught by Wright, since they are known structural alternatives for determination of viscosity of a solution.

Regarding claims 33 and 34, Ballerstadt in view of Wright discloses all the elements of the claimed invention, as described above, except for the electromagnetic arrangement comprising a magnet and a coil for exciting the magnet and a microprocessor connected to the coil for sensing the generated magnetic field. Wright further teaches a magnet and coil for exciting the magnet (paragraph [0025]) and a microprocessor for sensing the excited field (paragraphs [0026]-[0029], in order to ensure accuracy of viscosity measurements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Ballerstadt and Wright with an excitatory magnet and coil, and a microprocessor for measuring a generated magnetic field, as further taught by Wright, in order to ensure accuracy of viscosity measurements.

Allowable Subject Matter

8. The prior art of record fails to anticipate or make obvious the invention of claim 32, including, *inter-alia*, a blood glucose concentration sensor system comprising an implantable sensor in the form of a glucose-penetrable ampoule containing a sensitive liquid and a user device configured to be worn on a user's skin that controls measurement of the viscosity of the mixture created by the glucose and sensitive liquid and evaluation of the measurement, where the viscosity is measured by observing the oscillatory behavior of an oscillating element disposed in the implantable sensor and

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excited to oscillation by an oscillating magnetic field, and where the sensor also includes a plastic part disposed in the implantable sensor that confines the liquid volume, supports the oscillating element, and has an elongated bore into which an arm disposed on the magnet projects such that the liquids are mixed.

The prior art of record fails to anticipate or make obvious the invention of claims 36-46, including, *inter-alia*, a blood glucose concentration sensor system comprising an implantable sensor in the form of a glucose-penetrable ampoule containing a sensitive liquid and a user device configured to be worn on a user's skin that controls measurement of the viscosity of the mixture created by the glucose and sensitive liquid and evaluation of the measurement, where the viscosity is measured by observing the rotation of a measuring element disposed in the implantable sensor, where the element is driven by a driving magnet also disposed in the implantable sensor, and the rotations are analyzed based on their decay behavior after the driving magnet is turned off.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6267002 to Ehwald, which discloses similar inventions.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735